

**REMARKS**

Reconsideration is requested.

Claims 1-74 have been canceled, without prejudice. Claims 75-85 are pending.

The specification has been amended to include a cross-reference to the parent application. No new matter has been added.

To the extent not obviated by the above amendments, the Section 112, first paragraph, rejection of claims 75-85 stated on pages 2-5 of the Office Action dated October 6, 2003 (Paper No. 46), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

As with the restriction requirement of November 19, 2002, the applicants respectfully submit that the Examiner has again been inconsistent in prosecution of this application. See, page 2 of the Petition Decision dated March 19, 2003, along with the applicants Response of December 19, 2002 and the allowed claims of U.S. Patent No. 6,180,768 B1 which are attached thereto. Specifically, the Examiner now asserts that polynucleotide sequences which are "unique to at least one of the new subtypes" recited in claim 75 is not supported by an adequate written description. The same language however was allowed by this same Examiner and appear in U.S. Patent No. 6,180,768 B1 which was scheduled to issue January 30, 2001. None of the case law cited by the Examiner in support of the Section 112, first paragraph, rejection of Paper No. 46 is believed to have been rendered subsequent to the present Examiner's finding that the present specification adequately described the now objected-to language. The Examiner is requested to issue withdrawal the Section 112, first paragraph, rejection as the same is unfounded.

One of ordinary skill in the art will appreciate that the recitation of "unique to" is extensively and clearly defined in the present application at, for example, page 8, lines 25-33. Moreover, the "unique to" recitation will be appreciated by one of ordinary skill in the art to be synonymous with "type- or subtype-specific" as is clearly indicated on page 8, lines 32-33 of the specification. The Examiner is further requested to see the claims attached hereto from U.S. Patent Nos. 6,548,244; 5,882,852 and 5,514,539, for example, wherein the Patent Office is granted claims reciting the objected-to or synonymous phrases. The specification clearly describes the claimed invention and one of ordinary skill in the art would appreciate that the applicants were in possession of the claimed invention at the time the application was filed. The present Examiner previously recognized as much and is requested to be consistent in this regard as well as all aspects of the prosecution of the present application.

The Examiner is further urged to appreciate that any HCV type or subtype is first identified by characterization of a prototype isolate (see, paragraphs spanning pages 1 and 2 of the present specification). Further, identification of a prototype sequence of a new type/subtype defines for one of ordinary skill in the art the borders for classifying later found similar isolates in a known-type/subtype. See, page 2, lines 14-16 of the specification. This practice will be well recognized by one of ordinary skill in the art in defining genotypes of not only HCV but also HBV, HIV and HPV, for example.

Moreover, the specification clearly defines, for example, on pages 10 and 11, guidelines for defining HCV types/subtypes as well as the well-known methodology to achieve this goal, such as determining sequence homology and/or nucleotide distance. Accordingly, the applicants believe the specification will be recognized by one of

ordinary skill in the art to clearly describe the presently claimed invention. Finally, the applicants submit that with the Examiner's reasoning there would be no possibility to obtain claims reciting sequence homology or identity percentages less than 100% whereas the Patent Office clearly has granted claims to nucleotide sequences, for example, which include some variability, i.e., less than 100% sequence similarity to a specifically disclosed sequence.

Withdrawal of the Section 112, first paragraph, rejection of claims 75-85 is requested.

To the extent not obviated by the above, the Section 112, second paragraph, rejection of claims 75-85 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

As for the metes and bounds of the phrase recited in paragraph 2 on page 5 of Paper No. 46, the applicants again note that even the Examiner, as representative of one of ordinary skill in the art, appreciated the metes and bounds of the recited phrase when allowing similar claims in this application which was scheduled to issue as U.S. Patent No. 6,180,768 B1, a copy of which was previously provided with the applicants Response of December 19, 2002. The applicants submit that the claims are definite for the reasons noted above and the Examiner is further requested to again see the attached claims from patents issued by the U.S. Patent Office.

As for the Examiner's objection to the recitation of "a part of a sequence which is unique", the applicants note that the claims do not recite the same. More specifically, the unamended claim 76 recites "a part of said polynucleic acid" the distinction is important as "polynucleic acid" is defined in the paragraph spanning pages 7 and 8 of

the present specification as a nucleic acid sequence which may contain at least five contiguous nucleotides in common with the complete nucleotide sequence such that one of ordinary skill in the art reading the claims in light of the specification will appreciate the metes and bounds of the claimed invention.

As for the Examiner's objection to claim 80, the same has been amended above to advance prosecution, without prejudice. Moreover, claims 82-85 have been amended according to the Examiner's helpful suggestion on page 5 of Paper No. 46, to advance prosecution.

The claims are submitted to be definite and withdrawal of the Section 112, second paragraph, rejection of claims 75-85 is requested.

The Section 102 rejection of claims 75-85 over Qu, et al. (Journal of General Virology 75 (5), 1994, 1063-1070) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

Again, the applicants note that the present Examiner cited Qu, et al. earlier in prosecution and the applicants overcame the same. See, the face page of U.S. Patent No. 6,6180,768 B1, a copy of which was submitted with the applicants Response of December 19, 2002. The claims continue to be patentable over Qu as the Examiner has, with due respect, not interpreted the claims in light of the specification. Qu fails to teach sequences which are unique to at least one of the HCV types or subtypes as presently claimed. The Examiner is requested to see the above citation of the specification with regard to the definition of a polynucleic acid.

Withdrawal of the Section 102 rejection of claims 75-85 over Qu, et al. is requested.

Maertens et al  
Appl. No. 08/836,075  
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In view of the above, the claims are submitted to be in condition for allowance  
and a Notice to that effect is requested.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



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